

Multivariate analysis demonstrated that 2-year MACE rate was related to post-procedural minimal lumen diameter < 2.48 mm ($p = 0.013$), previous myocardial infarction ($p = 0.0206$), stent diameter of 3 mm ($p = 0.0325$) and hypertension ($p = 0.0422$). Conclusion: In comparison with DS-, these results show that DS+ has a similar rate of cardiac events at long-term follow-up and don't reduce the incidence late restenosis.

1078-14

Stents Covered by Autologous Venous Grafts in Human Coronary Arteries: Five-year Follow-up

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Background: The mid-term results after the implantation of autologous venous-graft covered stents (AVGCS) in human coronary arteries were favorable. The aim of our study was to present the long-term results of this technique. Moreover, a comparison was performed with the long-term results of uncovered stents. **Methods:** A venous graft was removed from an upper limb. Conventional stents then were covered either both internally and externally, or only externally by autologous venous grafts. Fifty-eight AVGCS were implanted in 56 patients, including 16 patients with acute coronary syndromes (ACS). Additionally, in the control group we enrolled 114 patients, in whom 138 uncovered stents were implanted including 38 patients with ACS. The demographic characteristics of the two groups were similar. **Results:** The procedure was successful in all patients. Acute thrombosis was observed in 3 patients of the control group. One patient with an AVGCS presented with subacute thrombosis. The restenosis rate was 13.3% in covered stents vs 20.8% ($p=NS$). All patients were examined clinically or interviewed by telephone communication at a mean of 62.4 ± 14.5 months in AVGCS group and 65.3 ± 12.7 months in the control group. The minimal lumen diameter had a trend to be greater in the AVGCS group at follow-up (2.22 ± 0.9 vs 2.10 ± 0.9 mm, $p=0.07$). The target vessel revascularization rate was 14% in the AVGCS group vs 17.1% in the control group ($p=NS$). The event-free survival rate at 4 years was 82% in the AVGCS vs 79% in the control group ($p=NS$). The event-free survival rate in ACS was 92% in AVGCS versus 75% in the control group, respectively ($P = 0.08$). Stents covered by thicker venous grafts were associated with improved clinical outcome. **Conclusions:** Stents covered by autologous venous grafts may be safely prepared without complications. The long-term results after AVGCS implantation showed that covered stents by venous grafts are not associated with late complications, which are related to the technique.

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Randomized Comparison of Gold-Coated NIR Stents With Uncoated NIR Stents in Patients With Coronary Artery Disease

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Background: Gold coatings enhance the radiopacity of steel stents, facilitating stent deployment into the target lesion. However, it remains uncertain whether gold coatings are a risk factor for restenosis after coronary stenting. The aim of this study was to determine whether gold-coatings increase the risk of in-stent restenosis in patients with coronary artery disease.

Methods: Two hundred and ten patients with 210 lesions (diameter stenosis > 50%, lesion length 2.5 mm) were randomly assigned to receive either an uncoated NIR stent group (Group I, $n=105$) or a gold-coated NIR stent group (Group II, $n=105$). The primary end point was angiographic restenosis at 6 months follow-up, and the secondary end point was major adverse cardiac events during 9 months.

Results: The baseline characteristics were similar between the two groups. Procedural success rate was 99.0% in group I and 100% in group II. In-hospital events did not occur in any patients. Angiographic follow-up were obtained in 169 patients (81.3% of those eligible), and the rates of angiographic restenosis were 27.1% in group I, and 44.0% in group II ($p<0.05$). Acute gain was not different between the two groups. However, late loss and loss index were significantly higher in group II than in group I ($P<0.05$). There was a trend of a higher incidence of major adverse cardiac events in group I than in group II (16.2% vs 26.7%, respectively, $p=0.06$).

Conclusion: Gold coatings may increase the risk of restenosis after coronary stenting.

1078-16

The Morphological and Histological Findings of Restenosis After Self-Expanding Biodegradable Coronary Stent Implantation

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Background: We have reported the low restenosis rate of Igaki-Tamai biodegradable self-expanding stent within 6 months in the human coronary arteries. We analyzed the morphology and histology of in-stent restenosis of the stent and initial outcomes of target lesion revascularization (TLR). **Method:** Sixty-three lesions in 50 patients underwent poly-L-lactic acid (PLLA) stent implantation for coronary artery stenosis. Eleven lesions (17.5%) in 10 patients revealed restenosis (%diameter stenosis > 50% at follow-up) and 6 lesions in 5 patients received TLR within 6 months. We assessed an angiographic classification of in-stent restenosis according to the geographic distribution of intimal hyperplasia. Removed tissues of restenosis by directional coronary atherectomy (DCA) were histologically examined by light-microscope and electron-microscope. **Results:** The reference vessel diameter of 11 restenotic lesions before stent implantation was 2.97 ± 0.49 mm and the lesion length was 12.2 ± 4.5 mm by quantitative coronary angiography. The morphology of 11 in-stent restenosis were 2 focal body, 4 focal margin, 2 diffuse intras-

tent, 2 diffuse proliferative and 1 total occlusion. One focal marginal, 1 diffuse intrastent, 1 diffuse proliferative and 1 total occluded in-stent restenosis received repeat balloon angioplasty. One focal marginal and 1 diffuse intrastent in-stent restenosis received repeat angioplasty by DCA. The in-stent restenosis were easily dilated by balloon angioplasty and easily excised by DCA. The stent struts were also easily excised by DCA. No major cardiac events such as death, myocardial infarction or bypass surgery associated with repeat angioplasty developed within the follow-up period. The histological findings revealed that there were proliferation of fibroblastic cells with myxoid stromal component partially surrounding the stent materials and no evidence of thrombogenesis nor foreign body response. **Conclusions:** Repeat angioplasty for in-stent restenosis of Igaki-Tamai stent performed easily and safely. The morphology of in-stent restenosis was similar to that of metallic stents and histological findings suggest biocompatibility of PLLA stent.

1078-17

Causes of Death in Patients With In-Sent Restenosis

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Background: Stenting is standard treatment for coronary revascularization, and stents generally perform favorably with respect to patient survival. However, there have been no data reported on the causes of death with autopsy confirmation in patients with initially successful coronary stenting.

Methods: From an ongoing registry study of human coronary artery stents submitted for pathologic analysis, patients with coronary stents deployed ≥ 3 months antemortem were identified. Clinical history and autopsy findings were reviewed. Stents and coronary arteries underwent detailed histologic evaluation.

Results: The study group consisted of 67 patients (42 men, 25 women; age 59 ± 13 years) with coronary stenting performed a mean of 10 months antemortem. Coronary death (CD) accounted for 50/67 (75%) cases and non-CD was responsible for the remaining 17 (25%). In-stent restenosis (ISR) was present in 50 cases: 43/50 (86%) with CD and 7/17 (41%) with non-CD ($p<0.001$). Of the 50 ISR patients, death was associated with: (1) ISR alone, without severe atherosclerosis in other major coronary arteries, in 17 cases (34%); (2) ISR with severe atherosclerosis in ≥ 1 additional non-stented coronary artery in 23 cases (46%); and (3) complications following repeat revascularization (catheter-based or CABG) in 10 cases (20%), all with severe atherosclerosis in ≥ 1 additional non-stented coronary artery. Of patients with ISR, 35% were symptomatic prior to death or attempted revascularization. Acute thrombosis of non-stented coronary arteries was present in 5 patients, and late stent thrombosis was seen in an additional 5 cases (3 of which with associated ISR). Notably, 32 of the 50 cases of CD after stenting were sudden and unexpected (64%).

Conclusions: In patients dying after successful coronary stenting, >75% have ISR, of which a majority have multi-vessel coronary atherosclerosis involving non-stented arteries. Sudden coronary death is common. The data support long-term follow-up of patients with coronary stents to identify in-stent restenosis and progressive atherosclerosis to prevent late cardiac death.

1078-18

Local Delivery of Evans Blue Significantly Prevents In-Stent Restenosis in Patients With Acute Myocardial Infarction

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Background: Restenosis remains to be solved in coronary intervention. Especially, in-stent restenosis occurs more frequently in patients with acute myocardial infarction (AMI) than in those with angina pectoris. We evaluated the effect of local delivery of Evans blue dye on prevention of restenosis in patients with AMI.

Methods: Eighty-one patients with AMI, who were treated with primary stent, were randomized to two groups. In 41 patients, including 33 males and 8 females (59.0 ± 8.6 years old, mean \pm SD), we administered 1 ml of 2% Evans blue dye (20mg) by local delivery technique, using porous balloon catheter 3 weeks after the onset (Evans blue group). Residual 40 patients (34 males and 6 females, 61.4 ± 9.5 years old), consisted a control group without administration of Evans blue dye. Restenosis was defined as diameter stenosis more than 50% on coronary angiography (CAG) at 7-month follow-up.

Results: Stents used were Multi-Link and GFX stents in both groups, and there were no differences in lesion distribution, stent diameter, length, and ratio of both stents between two groups. Just after stent implantation, there were no differences between two groups in reference luminal diameter (3.28 ± 0.39 mm vs. 3.19 ± 0.33 mm, Evans blue group vs. control group), minimal luminal diameter (3.20 ± 0.31 mm vs. 3.07 ± 0.39 mm), and diameter stenosis ($2.3 \pm 6.1\%$ vs. $3.2 \pm 10.6\%$). All patients completed follow up CAG (mean, 7 months). At follow up CAG, reference luminal diameter was not different between Evans blue and control group (3.14 ± 0.43 mm vs. 3.15 ± 0.32 mm, ns). Minimal luminal diameter was significantly larger in Evans blue group (2.64 ± 0.79 mm vs. 1.91 ± 0.76 mm, $p<0.0005$). Diameter stenosis was significantly lower in Evans blue group ($17.2 \pm 19.1\%$ vs. $39.5 \pm 23.6\%$, $p<0.0005$). Restenosis rate was also significantly lower in Evans blue group (5% vs. 25%, $p<0.05$).

Conclusion: Local delivery of Evans blue dye significantly prevented in-stent intimal proliferation and restenosis in patients with AMI.